

8EHQ-0245-13326  
PUBLIC NOTICE COPY

8EHQ-95-13326 (A)  
4495 0000 115

February 6, 1995

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED  
P 253 155 586

OPPT Document Processing Center (7407)  
ATTN: Section 8(e) Coordinator  
Office of Pollution Prevention and Toxics (OPPT)  
US Environmental Protection Agency  
Washington, DC 20460

**COMPANY SANITIZED**

RE: TSCA Section 8(e) Notice

Dear Sir or Madam:

This notice is being submitted by Rhône-Poulenc Ag Company (RPAC) to the Environmental Protection Agency (EPA) in accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA), 15 USC § 2607 (e).

We are submitting the results of a toxicity study in rats on . Only limited quantities of this compound have been synthesized for research and development purposes.

RPAC claims the alpha-numeric designation and the specific chemical identity of the substance at issue to be confidential business information (CBI). The chemical substance may be nonconfidentially identified as a "heterocycle".

Test material was administered by gavage at doses of 1, 5, and 15 mg/kg/day (7 male rats/group) for 14 days. Decreases in thyroxine, increases in thyroid stimulating hormone, and increases in liver weight were observed at 5 and 15 mg/kg/day. Hepatic hypertrophy and mitosis and thyroid follicular hyperplasia were noted at all doses.

SUPPORT INFORMATION OF CONFIDENTIALITY CLAIMS

1. Claims of confidentiality are being made on behalf of RPAC.
2. RPAC asserts this claim of confidentiality until such time as a specific chemical is approved for use in the United States. In the event that the chemical is never approved, RPAC asserts that the CBI information should be provided permanent protection. The structure and use of the chemical are unique. Disclosure of this information would provide our competitors with information on facets of our business that would be detrimental to our competitive position.

95 FEB 13 AM 8:10

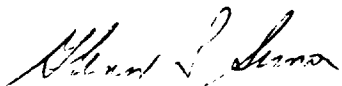
RECEIVED  
MAIL ROOM

3. The information claimed as confidential has not been previously disclosed to any other governmental agency or to EPA.
4. This information has been disclosed to only a very limited number of investigators outside of RPAC who have performed either toxicity or efficacy testing. These individuals operate under a strict secrecy agreement. Any individuals who may work with the chemical will have all health/toxicology information disclosed to them as well, but only on the basis of strict secrecy and respect for the CBI nature of the information.
5. Any individuals to whom the CBI is revealed are warned of the nature of the information. Further, they are informed of their obligations to maintain secrecy should they terminate their employment with RPAC.
6. None of the information claimed as confidential appears in or is referred to in any advertising or promotional materials for the chemical or the end product containing it, professional or trade publications, or any other media available to the public or to our competitors. Appropriate warnings do appear on safety data sheets, as RPAC considers that individuals who are requested to work with the chemicals have every right to know as much about the chemicals' toxicity as possible. Further, the information is only considered to be CBI with respect to the general public, insofar as our competitors could use the information in an unfairly competitive nature.
7. No previous confidentiality determinations have been made by EPA, other Federal agencies or courts in connection with this information.
8. RPAC believes that disclosure of this information to the general public would be likely to result in substantial harm to its competitive position. Disclosure of the **alpha numeric designation and chemical name** would provide some competitors with information about the specific chemistry of this area of our research and our business. Further, the type of toxicological testing being reported in the TSCA 8(e) notice would provide competitive information about this chemical's status in the research and development process and, therefore, the time remaining until commercialization.
9. A patent has not been issued for the specific chemical structure. However, the **generic** chemical structure is covered by a patent that is currently pending.
10. The chemical is not available commercially. It is in the earliest stages of research and development for pesticide use and is unlikely to be developed into a commercial product.
11. We believe that disclosure of the chemical name would allow a competitor to **synthesize** this chemical. RPAC has invested a large amount of time and money into research of **this** particular chemical family, and information on specific chemical structures would **harm our** competitive position.
12. Disclosure of the chemical structure might reveal information on processes **used to** synthesize this compound.
13. CAS number has not yet been assigned.
14. Currently, the chemical is not the subject of FIFRA regulation or reporting.

## PUBLIC NOTICE COPY

Further questions regarding this submission may be directed to the undersigned at 919-549-2222.

Sincerely,

A handwritten signature in black ink, appearing to read "Glenn S. Simon". The signature is fluid and cursive, with the first name "Glenn" being more prominent.

Glenn S. Simon, PhD, DABT  
Director of Toxicology

## Triage of 8(e) Submissions

Date sent to triage: 5/28/96

**NON-CAP**

**CAP**

Submission number: 13326A

TSCA Inventory: Y N **(D)**

Study type (circle appropriate):

Group 1 - Gordon Cash (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX **(SBTOX)** SEN w/NEUR

Group 3 - HERD (1 copy each)

STOX CTOX EPI RTOX GTOX  
STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): \_\_\_\_\_

Notes:

- ☒ This is the **original** 8(e) submission; refile after triage evaluation.
- ☐ This **original** submission has been **split**; rejoin after triage evaluation.
- ☐ Other:

### Photocopies Needed for Triage Evaluation

entire document: **(0)** 1 2 3

front section and CECATS: **(0)** 1 2 3

Initials: JW

Date: 5/23/96

## CE/CATS DATA:

Submission # 8ELHQ. 0295-13326<sup>5</sup> SEQ A

## TYPE (INT. SUPP FLWP)

SUBMITTER NAME: Rhone-Poulenc Ag  
Company

## INFORMATION REQUESTED: FLWP DATE:

0501 NO INFO REQUESTED  
0502 INFO REQUESTED (TECH)  
0503 INFO REQUESTED (VOL ACTIONS)  
0504 INFO REQUESTED (REPORTING RATIONALE)  
DISPOSITION:  
0639 REFER TO CHEMICAL SCREENING  
0678 CAP NOTICE

## VOLUNTARY ACTIONS:

0401 NO ACTION REPORTED  
0402 STUDIES PLANNED/UNDERWAY  
0403 NOTIFICATION OF WORKER/OTHERS  
0404 LABEL/MSDS CHANGES  
0405 PROCESS/HANDLING CHANGES  
0406 APP/USE DISCONTINUED  
0407 PRODUCTION DISCONTINUED  
0408 CONFIDENTIAL

SUB. DATE:

02/06/95

OTS DATE:

02/13/95

CSRAD DATE:

03/01/95

## CHEMICAL NAME:

heterocycle

CAS#

Confident

## INFORMATION TYPE:

0201 ONCO (HUMAN) 01 02 04  
0202 ONCO (ANIMAL) 01 02 04  
0203 CELL TRANS (IN VITRO) 01 02 04  
0204 MUTA (IN VITRO) 01 02 04  
0205 MUTA (IN VIVO) 01 02 04  
0206 REPRO/TERATO (HUMAN) 01 02 04  
0207 REPRO/TERATO (ANIMAL) 01 02 04  
0208 NEURO (HUMAN) 01 02 04  
0209 NEURO (ANIMAL) 01 02 04  
0210 ACUTE TOX. (HUMAN) 01 02 04  
0211 CHR. TOX. (HUMAN) 01 02 04  
0212 ACUTE TOX. (ANIMAL) 01 02 04  
0213 SUB ACUTE TOX (ANIMAL) 01 02 04  
0214 SUB CHRONIC TOX (ANIMAL) 01 02 04  
0215 CHRONIC TOX (ANIMAL) 01 02 04

P F C

## INFORMATION TYPE:

0216 EPI/CLIN 01 02 04  
0217 HUMAN EXPOS (PROD CONTAM) 01 02 04  
0218 HUMAN EXPOS (ACCIDENTAL) 01 02 04  
0219 HUMAN EXPOS (MONITORING) 01 02 04  
0220 ECO/AQUA TOX 01 02 04  
0221 ENV. OCCURREL/FATE 01 02 04  
0222 EMER INCI OF ENV CONTAM 01 02 04  
0223 RESPONSE REQUEST DELAY 01 02 04  
0224 PROD/COMP/CHEM ID 01 02 04  
0225 REPORTING RATIONALE 01 02 04  
0226 CONFIDENTIAL 01 02 04  
0227 ALLERG (HUMAN) 01 02 04  
0228 ALLERG (ANIMAL) 01 02 04  
0239 METAB/PHARMACO (ANIMAL) 01 02 04  
0240 METAB/PHARMACO (HUMAN) 01 02 04

P F C

## INFORMATION TYPE:

0241 IMMUNO (ANIMAL) 01 02 04  
0242 IMMUNO (HUMAN) 01 02 04  
0243 CHEM/PHYS PROP 01 02 04  
0244 CLASTO (IN VITRO) 01 02 04  
0245 CLASTO (ANIMAL) 01 02 04  
0246 CLASTO (HUMAN) 01 02 04  
0247 DNA DAM/REPAIR 01 02 04  
0248 PROD/USE/PROC 01 02 04  
0251 MSDS 01 02 04  
0299 OTHER 01 02 04

P F C

## TRIAGE DATA:

## NON-CBI INVENTORY

YES (CONTINUE)

NO (DROP)

DETERMINE

## ONGOING REVIEW:

YES (DROP/REFER)

NO (CONTINUE)

REFER:

## SPECIES

RAT

## TOXICOLOGICAL CONCERN:

LOW

MED

HIGH

## USE:

R: D

## PRODUCTION:

## COMMENTS:

13326A

H

Subacute oral toxicity in rats is of high concern. Male rats (7/dose) received oral gavage doses of 1, 5, and 15 mg/kg/day for 14 days. Decreased thyroxine, increased thyroid-stimulating hormone, and increased liver weight were observed at  $\geq 5$  mg/kg/day. Hepatic hypertrophy and mitosis and thyroid follicular hyperplasia were noted at all dose levels.